D1385B 2/2/98

DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

February 6, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Drewett, Corporate Risk Manager
Lincare, Inc.
19337 U.S. 19 North, Suite 500
Clearwater, FL 34862

PURGED

Ref. # - DEN-98-06

Dear Mr. Drewett:

During an inspection of your firm, Lincare, Inc., 1500 North 320 West, Unit L, Layton, UT, 84041, on November 24-25, 1997, Consumer Safety Officer James E. Moore, II determined that your firm transfills Liquid Medical Oxygen U.S.P. to patient home cryogenic units. Medical Oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your product, Liquid Oxygen, U.S.P., is adulterated under section 502(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (GMPs) under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection included, but were not limited to the following:

1. Failure to test each lot of liquid oxygen transfilled from the stand tank to vehicle mounted vessels [21 CFR 211.165(a)]. The filling of vehicle mounted vessels is considered to constitute a single batch; as such, each batch must be tested for identity and purity.

2. Failure to validate your procedure which uses a stainless steel cylinder (hoke bomb) to sample and transport the liquid oxygen in the bulk oxygen stand tank for identity and strength testing prior to transfilling to home cryogenic units [21 CFR 211.110].

3. Failure to document the method of analysis used to test liquid oxygen to assure compliance with established specifications [21 CFR 194(a)(2)]. For example, the Certificate of Analysis does not specify the method used to determine purity and identity testing of liquid oxygen.

4. Failure to identify the liquid oxygen in each vehicle mounted vessel after filling from the stand tank with a lot or control number that permits determination of the history of the manufacture and control of the batch. [21 CFR 211.130(c)]. Again, each filling of the vehicle mounted vessels constitutes a new batch.

5. Failure to store bulk liquid oxygen under quarantine until the product has been tested or examined, as appropriate, and released. [21 CFR 211.82(b)]. For example, you do not maintain any type of security or control from contamination over your leased bulk storage tank.

In addition, your Oxygen U.S.P. is not labeled properly as per the Compressed Gas Association's petition granted by the FDA on September 19, 1996, in that the following statement does not appear on your product: "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal law prohibits dispensing without prescription."

At the conclusion of this inspection, Consumer Safety Officer Moore issued a written report of observations (FDA 483) to Mr. Kirk J. Tidwell, Center Manager. A copy of that report is enclosed for your reference.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As President, it is your responsibility to assure adherence with all requirements of the Act and Good Manufacturing Regulations.

These deviations may be indicative of corporate wide non-compliance. We recommend that internal audits be conducted at your medical gas facility and appropriate action be taken to assure that similar violations are not occurring at other locations.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Ms. Shelly L. Maifarth, Compliance Officer, at the above address.

Sincerely,

Gary C. Dean
District Director

Enclosures
As Stated in Letter

cc: Kirk J. Tidwell, Center Manager
Lincare, Inc.
1500 North 320 West, Unit L
Layton, UT 84041

Ms. Mary Kay Smith, Regional Administrator
Health Care Financing Administration, DHHS Region VIII
Byron G. Rogers Federal Building
1961 Stout Street, Fifth Floor
Denver, Colorado 80294-3538

bcc: [redacted]

SLM
2-4-98

ec: [redacted]

SLM.dw.020598

PURGED